

Amendments to the Specification:

Please add the following new paragraphs after the paragraph ending at page 2, line 8:

U.S. Patent Application Serial No. 09/466,559 (now U.S. Patent No. 6,534,063) and U.S. Patent Application Serial No. 09/707,395 (now U.S. Patent No. 6,632,429) relate generally to a method for treating individuals diagnosed with a form of PDD (pervasive development disorder) and other disorders such as ADD (attention deficit disorder) and ADHD (attention deficit hyperactivity disorder). More specifically, the present invention is directed to therapeutic methods for treating individuals with such disorders by administering secretin, other neuropeptides, peptides, and/or digestive enzymes, as well as a prognosticative method for determining the potential effectiveness of the administration of secretin, other neuropeptides, peptides, and/or digestive enzymes for the treatment of such disorders. The spectrum of PDDs include disorders such as Autism, Aspergers, ADD, and ADHD. PDDs are typically characterized by multiple distortions in the development of basic psychological functions that are involved in the development of social skills and language, such as attention, perception reality testing and motor movement. In addition, many children diagnosed with Autism, for example, suffer from primary diffuse gastrointestinal problems such as protracted diarrhea and constipation.

The invention involves determining the presence of abnormal protein digestion of individuals, especially children, by measuring the chymotrypsin levels so as to determine if the individual is likely to benefit from the administration of secretin, digestive enzymes, peptides and/or neuropeptides. Tests were performed to measure the fecal chymotrypsin levels (referred to herein as Fecal Chymotrypsin Test) in children who span the entire PDD spectrum and whose symptomatology place them in this DSM IV category. Such tests revealed that a majority of the children diagnosed with autism, ADD and ADHD, for example, had abnormal chymotrypsin levels. Those children having abnormal levels of chymotrypsin in their stools are considered candidates for secretin administration. Other factors that may be considered in determining

which children are potential candidates for secretin administration aside from the fecal chymotrypsin levels include a previously diagnosed history of autism, a history of gastrointestinal (GI) dysfunction, including any history of protracted diarrhea or constipation lasting for weeks or months, as well as a self-limiting diet consisting primarily of carbohydrates. Upon determining that a given child was likely to benefit from secretin administration based on the results of the fecal chymotrypsin test, the child was administered a CARS (Childhood Autism Rating Scale) test prior to being scheduled for secretin infusion.

Another experiment was performed to determine the effect of the administration of digestive enzymes to Autistic children. Each of the 17 autistic children were administered digestive/pancreatic enzymes comprising amylases, proteases, lipases, sucrases, maltases, and other digestive/pancreatic enzymes including trypsin and chymotrypsin. The measured fecal chymotrypsin levels of at least 16 of the 17 autistic children were found to increase 6 months post-digestive enzyme administration. Furthermore, a notable decrease in autistic symptomatology of each of the 17 autistic children was observed as a result of digestive/pancreatic enzyme administration.